360° CLINICAL SERIES

LIBERTY 360° ECONOMIC VALUE ANALYSIS

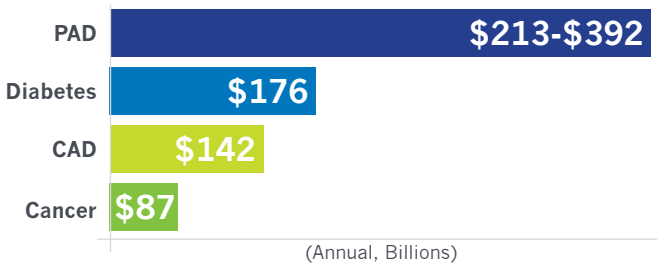
The LIBERTY 360° study represents the largest, contemporary, **real-world experience with various endovascular strategies across the full range of Rutherford Category (RC) patients and includes any FDA-approved or cleared technologies** to treat claudication and CLI. Sites included hospital and office-based labs (OBLs).

The LIBERTY Economic Value Analysis examined the relationship between different patient characteristics and acute and long-term costs for patients undergoing peripheral vascular interventions (PVI).

20 MILLION PEOPLE

WITH PAD IN THE US.[1]

Large economic burden compared to other chronic diseases in health care expenditures.[2]

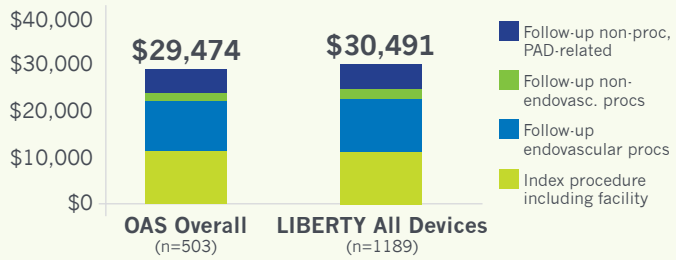


2015 Direct costs in the United States: PAD & CAD costs inflated to 2014 $.

LIBERTY 360° ECONOMIC ANALYSIS KEY FINDINGS[3]

2-year cost benefit with the Orbital Atherectomy System (OAS).

2-YEAR COSTS (RC 2-6)



Hospital costs used standard "bottom-up" cost accounting methods based on detailed resources collected at the time of the procedure and 2018 acquisition costs. Costs assessed for PAD-related physician fees, outpatient procedures, diagnostic tests, office visits and days in rehabilitation, skilled nursing and other chronic care facilities using the 2018 Medicare fee schedule.

Lower index hospital and 2-year costs with OAS.

PAD-RELATED COSTS BY DEVICE

	Any OAS (n=503)	Any DCB (n=152)	Any DES (n=79)
Index Hospital	$11,729	$13,653	$13,063
Cumulative 2-year	$29,474	$31,669	$35,326

Mean PAD-related costs up to 2 years following the index procedure according to specific devices used during the index procedure (non-mutually exclusive categories), adjusted for censoring.

LIBERTY 360° PREDICTORS OF 2-YEAR COSTS (all devices)

FEMALE SEX

17% ↑ Female Sex vs. Male Sex

RUTHERFORD CATEGORY

23% ↑ RC 4,5 vs. RC 2,3

27% ↑ RC 6 vs. RC 2,3

CTO

26% ↑ ≥1 CTO at baseline vs. no CTO at baseline

LESION

76% ↑ Pedal lesion location vs. SFA lesion location

CALCIUM

PARC calcification grade

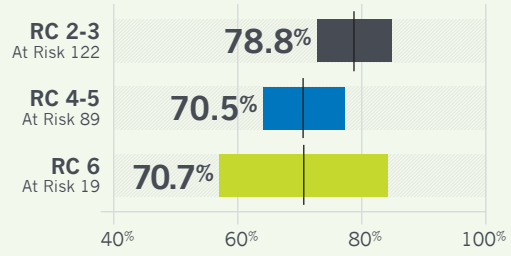
18% ↑ Grade 4 lesion vs. Grade O lesion

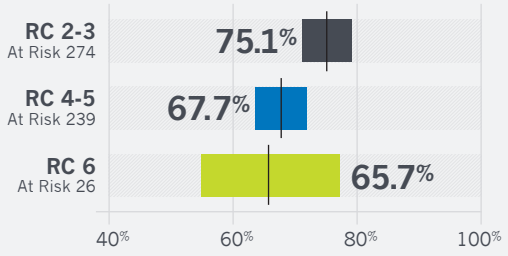
LIBERTY 360º 2-YEAR CLINICAL OUTCOMES[4] *(Kaplan-Meier Estimates)*

Despite complex demographics (e.g., history of LE PVI, history of MI, CTOs, lesion length) in this real-world study, there was high freedom from major amputation, TVR/TLR, and amputation free survival at 2 years.

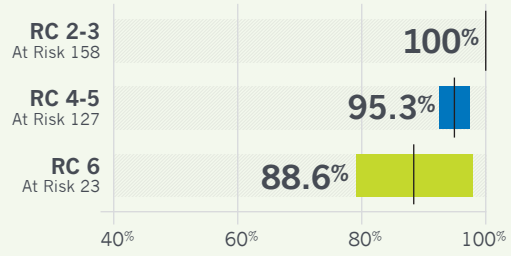
LIBERTY 360° OAS	LIBERTY 360° ALL DEVICES

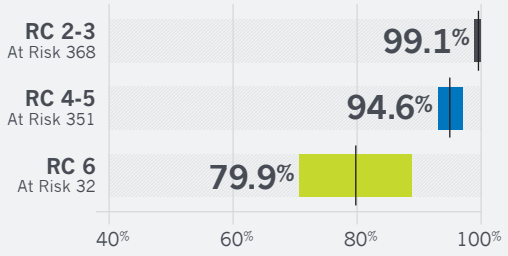
FREEDOM FROM TVR/TLR



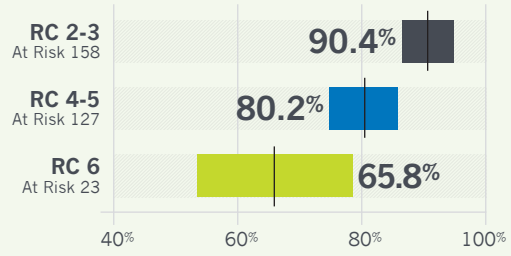


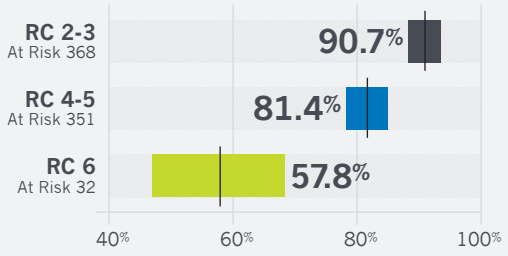
FREEDOM FROM MAJOR AMPUTATION ON TARGET LIMB





AMPUTATION-FREE SURVIVAL*





** Amputation free survival defined as freedom from death and target limb major amputation.*

Greenwood's method used to obtain the 95% confidence interval for the estimate.

[1] Yost ML. Critical limb ischemia. Volume I. Unites States epidemiology. 2016 Supplement.
[2] Yost ML. The Economic Cost of PAD, CLI & Venous Disease: How Big is the Market? Presented at NCVH 2016.
[3] Magnuson EA., et al. Two-year PAD-related health care costs in patients undergoing lower extremity endovascular revascularization: Results from the LIBERTY 360° trial. J Med Econ. 2021;24(1):570-580.
[4] CSI Data On File

LIBERTY 360º is sponsored by Cardiovascular Systems, Inc. (ClinicalTrials.gov NCT01855412)

Brief Statement: The Diamondback 360® Peripheral Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. Contraindications for the system include for use in coronary arteries, bypass grafts, stents, or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

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